

Exhibit P

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Attorney Docket No. 780-A02-014-8
Peter M. BONUTTI : Confirmation No. : 8298
Application No.: 10/003,996 : Art Unit: 3733
Filed: November 15, 2001 : Examiner: Mary C. Hoffman

Title: *APPARATUS AND METHOD FOR TISSUE REMOVAL*

PETITION UNDER 37 C.F.R. §1.182 TO WITHDRAW
A RECORDED TERMINAL DISCLAIMER

Mail Stop: Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant hereby petitions for withdrawal of the Terminal Disclaimer under 37 C.F.R. §1.321(c) filed on March 31, 2003 and recorded on June 23, 2003 in the above-identified patent application. This Terminal Disclaimer addresses the rejection of claims 36-40, 48, and 49 under obviousness-type double patenting over claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317.

Table of Contents for this Petition and Attached Exhibits

Petition (6 pages) - Begins on page 2.

- Exhibit A: Copy of Claims as Originally Filed on November 15, 2001 (9 pages)
- Exhibit B: Copy of Claims Rejected under Obviousness-type Double Patenting (2 pages)
- Exhibit C: Copy of Patent Claims Cited in the Double Patenting Rejection (2 pages)
- Exhibit D: Copy of First Non-Final Office Action Mailed on December 30, 2002 (8 pages)
- Exhibit E: Copy of U.S. Patent 5,403,317 Issued on April 4, 1995 (14 pages)
- Exhibit F: Copy of Response to First Office Action Filed on March 31, 2003 (14 pages)
- Exhibit G: Copy of Terminal Disclaimer under 37 C.F.R. §1.321(c) Filed on March 31, 2003 (2 pages, Terminal Disclaimer; 15 pages Attachment)
- Exhibit H: Copy of Second Non-Final Office Action Mailed on June 23, 2003 (8 pages)
- Exhibit I: Copy of Transaction History Obtained from PAIR on June 10, 2010 (3 pages)
- Exhibit J: Copy of Current Office Action Mailed on April 15, 2010 (5 pages)
- Exhibit K: Copy of Claims as Currently Pending (10 pages)

Statement of Case:

The above-identified application was filed on November 15, 2001 with forty-two claims, including, claim 1 of the parent application (U.S. Application Serial Number 09/483,676, filed on January 14, 2000) and claims 36-76 added by a Preliminary Amendment filed concurrently with the application. Claims 2-35 of the parent application were cancelled in the Preliminary Amendment. A copy of the claims as originally filed is attached hereto as Exhibit A.

The first Office Action was issued by Examiner Jessica R. Baxter on December 30, 2002 and included an obviousness-type double patenting rejection as follows:

Claims 36-40, 48, and 49 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a surgical procedure comprising removing tissue from a first location in a patient's body under the influence of suction by rotating a cutting tool, separating one or more components from at least a portion of the tissue removed by centrifugation, packing the tissue, adding a substance to the tissue after separating one or more components from the tissue, and implanting the tissue at a second location in the patient's body.

A copy of the rejected claims 36-40, 48, and 49 and a copy of the patent claims 1, 5, 7, and 19-21 are attached hereto as Exhibits B and C, respectively. The Office Action also included further rejections of the claims and an indication of allowable subject matter in claims 41, 56, 71, 72, 75, and 76. A copy of the Office Action and a copy of U.S. Patent No. 5,403,317 are attached hereto as Exhibits D and E, respectively.

In response to the obviousness-type double patenting rejection Applicant submitted a Terminal Disclaimer under 37 C.F.R. §1.321(c) with the Amendment filed on March 31, 2003. This Terminal Disclaimer stated, *inter alia*, the following:

Petitioner hereby disclaims the terminal part of any patent granted on the above-identified application that would extend beyond the expiration date of U.S. Patent No. 5,403,317 issued on April 4, 1995.

A copy of the Amendment and a copy of the Terminal Disclaimer are attached hereto as Exhibits F and G, respectively.

The Terminal Disclaimer was accepted and recorded as indicated in the Office Action of June 23, 2003. A copy of this Office Action is attached hereto as Exhibit H.

Despite the filing of the Terminal Disclaimer and the indication of allowable subject matter, prosecution continued and has been ongoing for nine years. The inaction of the Office contributed significantly to the delay. For example, responsibility for the case was supposedly transferred to a new Examiner after Examiner Baxter resigned from her position, however this transfer does not appear to have been timely as no substantive action was taken in the application from November 2004 to October 2006. This lapse in prosecution can be verified by the Transaction History, a copy of which is attached hereto as Exhibit I.

Claims 36-39, 41-44, 46, 47, 49, 57-60, 69-71, and 73-96, as now pending, have been indicated as allowable by Examiner Mary Hoffman. A copy of the current Office Action (mailed on April 15, 2010) and a copy of the pending claims are attached hereto as Exhibits J and K, respectively.

Applicable Rule:

The basis for this petition is 37 C.F.R. §1.181-1.182. Rule §1.182 states, *inter alia*, the following:

All situations not specifically provided for in the regulations of this part (§ 1.181, Petition to the Director) will be decided in accordance with the merits of each situation by or under the authority of the Director, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(f).

The procedure for withdrawal of a recorded Terminal Disclaimer (before issuance of patent) is discussed at section 1490 VII A of the MPEP.

Analysis:

During prosecution of a patent application, the claim set can be, and usually is, altered in a variety of ways. Claims are amended, cancelled, added, and/or withdrawn. The scope of material encompassed by the claims is narrowed and/or expanded. As a result, allowed claims are often different, or at the very least somewhat evolved, from their original format.

Considering the changes that can occur, Applicant can request that any double patenting rejection made early in prosecution be temporarily held in abeyance and subsequently reevaluated when the rejected claims are in allowable form. However, this practice is not etched in stone and any action taken to address a double patenting rejection is dependent upon the objectives of the Applicant.

In the instant case, a Terminal Disclaimer was filed immediately in response to the rejection of claims 36-40, 48, and 49 over claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317. Applicant's reasons for this speedy filing are two-fold, desire to obtain an early allowance and desire to approach potential licensees with issued claims. These reasons are connected as a licensee is usually very happy with an early allowance and potential licensees view issued claims with more weight than potentially allowed claims.

The primary concern was the allowable subject matter indicated by Examiner Baxter (claims 41, 56, 71, 72, 75, and 76). Applicant reviewed the claims and decided that it would be prudent to pursue a quick allowance considering that obtaining allowable subject matter in an initial Office Action is rare. Furthermore, Applicant realized that arguing the merits of the double patenting rejection or requesting that it be held in abeyance would likely delay or prevent quick allowance. Thus, a Terminal Disclaimer was filed.

Also of concern is the nature of the field. Medical technology, especially surgical technology, does not stand still. New methods, products, and procedures are continually developed and introduced to the market. Thus, surgical technology is an extremely active area in intellectual property. Efficient patent prosecution and quick allowance of claims are necessary in order to attract licensees for new products/methods and to provide any existing licensees with relevant products/methods. Such concerns further motivated Applicant to file the Terminal Disclaimer.

Claims 36-39 and 49, originally rejected under obviousness-type double patenting, are now allowable. Considering that these claims have been amended multiple times since the first rejection, Applicant has reevaluated the propriety of the obviousness-type double patenting rejection.

Claims 36-39 and 49 are distinguishable both from claims 36-40, 48, and 49 as initially rejected (under obviousness-type double patenting) and from claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317.

Independent claim 36, as initially rejected, encompassed a surgical procedure to be conducted on a patient, the procedure comprising removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed (from the patient's body), and implanting the tissue at a second location in the patient's body after the components have been separated.

The steps of the surgical procedure, as now claimed in independent claim 36, have been expanded to include an additional step, *i.e.* packing the removed tissue into a desired shape after separating the components and prior to implanting at a second location. Additionally, the tissue removed is now further described as including blood and other body tissue. Thus, the scope of claim 36 as currently pending is distinguishable from the scope of the claim as initially rejected.

As does claim 36, independent claim 1 of U.S. Patent 5,403,317 encompasses a surgical procedure for removing and implanting tissue. However, claim 1 includes a step of compacting the tissue removed to decrease the volume of a mass of the tissue from a first volume to a second volume that is smaller than the first volume prior to implanting the tissue at a second location.

The step of "compacting tissue to decrease volume" involves consolidating or condensing tissue into a smaller form while the step of "packing tissue into a desired shape" involves arranging or collecting tissue but does not necessarily require that the volume of the tissue be decreased to be packed. Compacted tissue need not be shaped into any form. Further, a procedure including a step for packing tissue into a desired shape can be used in different clinical situations than a procedure in which tissue is compressed to fit into an opening or void. For example, tissue may be shaped to resemble bone and/or other body parts. Thus, from a comparison of the steps which distinguish the surgical procedure of claim 36 from the surgical procedure of patented claim 1; *i.e.* "packing tissue into a desired shape" vs. "compacting tissue to decrease volume", it is clear that the steps are neither identical nor mutually interchangeable within the surgical procedures. Accordingly, the step of packing tissue distinguishes the claims as currently pending from the patented claims.

Furthermore, claim 36, as currently pending, now specifies that the removed tissue to be packed includes blood and other body tissue. Blood contains the sticky clotting component fibrin and can be used to hold the tissue fragments together in the desired shape. There is no recitation in the patented claims that the tissue removed and compacted contains blood.

In addition to claims 1 and 7, patented claims 5 and 19-21 were cited in the obviousness-type double patenting rejection. Claims 5 and 19-21 require enclosing the removed tissue in biodegradable material (claim 5) or in a sac (claims 19-21). The rejected claims 36-39 and 49, as now pending, do not require any type of enclosure of tissue in biodegradable material or in a sac and are thus outside of the scope of the patented claims.

From the above discussion it is clear that claims 36-39 and 49 have changed in scope from claims 36-40, 48, and 49 as initially rejected, therefore the obviousness-type double patenting rejection is no longer applicable and should be withdrawn. Furthermore, it has been demonstrated that currently pending claims 36-39 and 49 are patentably distinguishable from claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317, therefore the Terminal Disclaimer should be nullified.

Conclusion:

Since it is now established that allowed claims 36-39 and 49 are in fact patentably distinct from claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317, Applicant respectfully requests that the recorded Terminal Disclaimer be withdrawn and any patent term extension to which he is entitled based upon delayed prosecution be granted

The fee for this Petition pursuant to 37 C.F.R. § 1.17(f) in the amount of \$400 is being paid via credit card. No other fees are believed to be due at this time. However, the Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account 503410.

Respectfully submitted,

/Paul D. Bianco/

Date: June 18, 2010

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